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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/728,665	12/05/2003	Satyanarayana Medicherla	219002032800	1249
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MORRISON & FOERSTER LLP 12531 HIGH BLUFF DRIVE SUITE 100 SAN DIEGO, CA 92130-2040			EXAMINER THOMAS, TIMOTHY P	
			ART UNIT 1614	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/728,665	Applicant(s) MEDICHERLA ET AL.	
	Examiner Timothy P. Thomas	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948). | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08).
Paper No(s)/Mail Date <u>3/23/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Application

1. Acknowledgment is made of the amendments to the claims filed with the response of 3/23/2007. Claims 7-8 and 10-11 are canceled. Claims 1 and 4 are amended. Claims 1-6 and 9 are pending and examined on the basis of the merits.
2. The supplemental Information Disclosure statement, filed with the response is acknowledged.

Response to Arguments

3. The rejection of claims 1-6 and 9 as being indefinite under 35 USC 112 2nd paragraph is withdrawn, due to the claim amendments.
4. The scope of enablement rejection of claims 1-6 and 9 under 35 USC 112 1st paragraph is withdrawn, due to the amendment of the claims.
5. Applicant's arguments filed 3/23/2007, have been fully considered but they are not persuasive.
6. The arguments with respect to the International Search Report are not persuasive; the reference provided by applicant does not provide the required publication information. The relevant section of 37 CFR 1.98 (Content of information disclosure statement), as printed in MPEP 609, is quoted:

"(b) (4) Each foreign patent or published foreign patent application listed in an information disclosure statement must be identified by the country or patent office which issued the patent or published the application, an

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appropriate document number, **and the publication date indicated on the patent or published application.**" (emphasis added)

However, since applicant requires the consideration of the search report, the WIPO publication containing that report has been considered by the examiner and listed on Form PTO-892.

7. In response to applicant's argument regarding the rejection of claims 1-6 and 9 under 35 USC 103, that there is no suggestion to combine the references, other than it would have been "obvious to try", the examiner does not agree. There is suggestion to combine the teachings in the reasonings explained in the previous Office Action from the teachings of both Mavunkel and Faustman that would provide motivation to combine the teachings to administer p38 MAPK inhibitors, including those that inhibit the alpha isoform to patients with type 1 diabetes.

Furthermore, the examiner also notes that "obvious to try", acknowledged by applicant as a reason for the combination of the references in the reply, has now been recognized by the courts as a valid motivation to show an invention is obvious. In *KSR International vs. Teleflex Inc.*; 82 USPQ 2d 1385 the court stated:

"A person of ordinary skill is also a person of ordinary creativity, not an automaton.

The same constricted analysis led the Court of Appeals to conclude, in error, that a patent claim cannot be proved obvious merely by showing that the combination of elements was "obvious to try." ...When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under §103." *KSR International vs. Teleflex Inc.*; 82 USPQ 2d 1385; p. 1397, C [5]-[6]

The conclusion is reached that a prima facie case of obviousness was made in the prior Office Action.

Applicant also argues concerning limitations of claims 2, 3, 6 and 9 that the Examiner dismissed the limitations as not further limiting the claimed method, which applicant argues is incorrect: the limitations of claims 2 and 3 provide additional information that could be used to identify a suitable candidate for treatment by the claimed method and claims 6 and 9 recite novel and non-obvious results of the claimed method not suggested by the cited art. Claim 1 has already identified candidates that the disclosure teaches are suitable for treatment by the methods, "patients in need thereof: in claim 1, i.e., patients with Type I diabetes. The Examiner interpreted the claim 2 and 3 limitations characteristics in a patient produced by the treatment. Even if these limitations are viewed as representing a subset of patients where the therapy is somehow more effective (which does not seem to be supported by the disclosure, since claim 1 indicates the therapy is effective for a patient with type I diabetes, without requiring any other characteristics in a patient population), a teaching of using the method to treat patients with type I diabetes will still render obvious (or anticipate) the method for a subpopulation of that same group, especially since there are no steps that involve testing or diagnosis for such a subpopulation in the method as claimed, i.e., the prior art contains the method steps, even as amended. The properties that result from the active method step is a natural outcome (or inherent) of administration of a p38 MAP kinase inhibitor, whether or not the property is disclosed in the prior art reference.

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As pointed out in the previous action, the burden has shifted to applicant to prove that the prior art subject matter does not possess the characteristics of these claims.

8. In response to applicant's argument regarding the rejection of claims 1-3, 5-6 and 9 under 35 USC 102, that Revesz does not teach the use of inhibitors of p38 MAP kinase generically, and without any mention of particular isoforms of the enzyme, the following rebuttal is made. A general teaching of inhibitors of p38 MAP kinase to treat type I diabetes is not required to anticipate the claims; what is required is one single p38 MAP kinase inhibitor (a specie) or a group of inhibitors (a subgenus, which is the case for this art) that are used to treat the disease claimed. That condition is met, the genus is anticipated. The argument that the isoforms claimed does not appear in the prior art is not relevant, either. The fact that applicant has disclosed the same subgenus of compounds (see specification, p. 16, top), and stated that "compounds useful in the practice of the present invention include...compounds of the formula [same as disclosed by Revesz, formula I]". This disclosure by applicant clearly indicates that these compounds possess the properties, as claimed, for use in the invention. The properties that applicant argues are not taught by Revesz, are an inherent property of or inherent with the administration of the compounds. As pointed out in the previous action, the burden has shifted to applicant to prove that the prior art subject matter does not possess the characteristics of these claims.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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10. Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The amendment to claim 1 incorporates the limitation that the p38 MAP kinase inhibitor inhibits the alpha isoform of the enzyme. Claim 4 permits said inhibitor to be selective for any (claimed in the alternative, "or") of the four enzyme isoforms, i.e., the scope of claim 4 contains subject matter, which is now outside of the scope of claim 1, on which it depends. Therefore, claim 4 is indefinite with regard to the metes and bounds of the beta, gamma and delta p38 isoform inhibition properties.

It is noted that this new rejection is necessitated by applicant's amendments.

11. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claims 1-3, 5-6 and 9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant is not in possession of an entire genus of p38 mitogen activated protein kinase inhibitor, which inhibits the alpha isoform of p38 MAP kinase. It is noted that this new rejection is necessitated by applicant's amendments.

The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application, of the specific subject matter later claimed by him. The courts have stated:

"To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that 'the inventor invented the claimed invention.'" *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997); *In re Gostelli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966." *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In *Regents of the University of California v. Eli Lilly & Co.* the court stated:

"A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *Fiers*, 984 F.2d at 1171, 25 USPQ2d 1601; *In re Smythe*, 480 F.2d 1376, 1383, 178 USPQ 279, 284985 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus ...") *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

The MPEP further states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP § 2163. The MPEP does state that for a generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. MPEP § 2163. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See

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MPEP § 2163. Although the MPEP does not define what constitute a sufficient number of representative species, the courts have indicated what do not constitute a representative number of species to adequately describe a broad generic. In *Gostelli*, the courts determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. *In re Gostelli*, 872, F.2d at 1012, 10 USPQ2d at 1618.

The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include "level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient." MPEP § 2163. While all of the factors have been considered, a sufficient amount for a *prima facie* case are discussed below.

In the instant case, the claims are drawn to a method of treating type I diabetes comprising administration of an effective amount of p38MAP kinase inhibitor, wherein the inhibitor inhibits the alpha isoform of p38.

(1) Level of skill and knowledge in the art:

The level of skill and knowledge in the art is high.

(2) Partial structure:

All of the examples were conducted with compound #25, which has the property of inhibiting the alpha isoform of p38 MAP kinase. The specification gives many

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compounds and classes of compounds that are inhibitors of p38, but does not identify any of these as inhibitors of the alpha isoform.

(3) Physical and/or chemical properties and (4) Functional characteristics:

The compound is required to be an inhibitor of the alpha isoform of p38 MAP kinase.

(5) Method of making the claimed invention:

Various methods are identified in the art to make the compounds. No methods are identified to make compounds that specifically inhibit the alpha isoform of p38 MAP kinase.

As stated *supra*, the MPEP states that written description for a genus can be achieved by a representative number of species within a broad generic. It is unquestionable that claim(s) 1-3, 5-6 and 9 is/are broad and generic, with respect to all possible compounds encompassed by the claims. The possible structural variations are limitless to any p38 MAP kinase inhibitor. Although the claims may recite some functional characteristics, the claims lack written description because there is no disclosure of a correlation between function and structure of the compounds beyond those compounds specifically disclosed in the examples in the specification. Moreover, the specification lacks sufficient variety of species to reflect this variance in the genus. While having written description of compound 25 and compounds identified in the specification tables and/or examples, the specification does not provide sufficient descriptive support for the myriad of compounds embraced by the claims.

The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736, F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.") Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

Conclusion

13. No claim is allowed.

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy P. Thomas whose telephone number is (571) 272-8994. The examiner can normally be reached on Monday-Thursday 6:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/TPT/
Timothy P. Thomas
Patent Examiner


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SUPERVISORY PATENT EXAMINER